

## REMARKS

This invention is directed to methods of treating renal fibrosis by the administration of quinazolinones. The specification and examples demonstrate the efficacy of halofuginone, a species of quinazolinone, for inhibition of the pathological progression of renal fibrosis.

### **Claim amendments:**

Pending claims 1-14 stand rejected. Claims 1-8 and 12-14 are hereby canceled, thereby rendering moot all rejections of these claims. Claim 9 has been amended to more clearly define the invention, thereby obviating the rejection of claim 9 and dependent claims 10 and 11 for lack of written description in the application as originally filed, as described below.

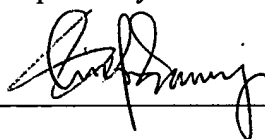
Claim 9 has been amended to recite a “method for attenuating the progression of renal fibrosis in a subject exposed to an inducer of renal fibrosis”, where the compound is administered “before the subject exhibits a renal fibrotic condition.” Original support for this amendment is found, e.g., on page 10, lines 8-12 (indicating that renal fibrosis can be induced by underlying pathology caused by diabetes, hypertension or autoimmune and other disorders); page 16, lines 15-16 (stating that renal mass reduction (RMR) is an inducer of renal fibrosis in rats), and in Examples 1 and 2 (where rats are exposed to an experimental inducer of renal fibrosis, i.e., RMR, followed 24 hours later by administration of halofuginone, which, over the subsequent 10 weeks attenuates the progression and development of a full-blown diseased state). Thus, no new matter has been added.

Claim 9 has also been amended to recite the step of administering a composition comprising a compound and a pharmaceutically acceptable carrier, rather than a compound in a pharmaceutically acceptable carrier. This reflects more accurately the original disclosure, e.g., on page 14, lines 16 and 17 (stating that “the composition preferably includes a pharmaceutically acceptable carrier for the compound”).

Claim 15 has been newly added to recite a method for preserving renal function after exposure to an inducer of renal fibrosis. Claims 16 and 17 have also been newly added and depend from newly added claim 15. Support for claims 15 and 16 is found, e.g., in Examples 1 and 2, on page 18, lines 20-24 and page 21, lines 9-11. Support for new claim 17 is found, e.g., at page 22, lines 4-10.

The amendments presented herein place the application in condition for allowance. Accordingly, applicants respectfully request that the Examiner enter the claim amendments presented herein, consider the foregoing remarks and allow the pending claims.

Respectfully submitted,



---

Jane T. Gunnison (Reg. No. 38,479)  
Barbara A. Ruskin (Reg. No. 39,350)  
Shilpi Banerjee (Reg. No. 53,965)  
Attorneys for Applicants

FISH & NEAVE LLP  
Customer No. 1473  
1251 Avenue of the Americas  
New York, New York 10020-1105  
Tel.: (212) 596-9000  
Fax: (212) 596-9090